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Alexandria, VA 22313-1450

On April 18, 2006

TOWNSEND and TOWNSEND and CREW LLP

By: Raen Karlin

PATENT
Attorney Docket No.: 02307E-
161500US
UC Reference: 2004-070-1

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Tao Jiang et al.

Application No.: 10/699,562

Filed: October 31, 2003

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Examiner: Dameron Levest Jones

Art Unit: 1618

RESPONSE TO RESTRICTION
REQUIREMENT

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
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Sir:

In response to the restriction requirement mailed October 18, 2005, Applicants elect Group 1, claims 1-48 and 51-56, drawn to molecules comprising A-X-B wherein SEQ ID NO:1 (PLGLAG) is utilized. For the purposes of searching, Applicants elect the species SEQ ID NO:13, which comprises portions A, X, B, and C.

The foregoing election is made with traverse, as the first 50 groups (compositions) set forth by the Examiner and the second 50 groups (methods of use) set forth by the Examiner all stem from a common concept and theory, and are thus related, as described below. Applicants therefore reserve the right to petition this requirement.

The present application contains generic composition claims and claims directed to methods of use. Of the 54 pending claims, two dependent claims recite a single

SEQ ID NO: (claims 41 and 42 recite SEQ ID NOS:1 and 2, respectively). No other sequences are listed in the claims. However, the Examiner has identified each of the 49 sequences listed in the specification, and created a separate Group to which the invention is restricted for each of these 49 sequences, for the composition and method claims, for a total of 100 Groups. In some cases, the sequences listed by the Examiner do not even represent the claimed invention. Applicants submit that the Examiner has improperly restricted individual claims into 100 Groups, and therefore has refused to examine the claims as drafted. Furthermore, the Examiner has improperly imported SEQ ID NOS: into the claims. Finally, although each of the inventions in Groups 1-50 and Groups 51-100, respectively, fall in the same class and subclass, the Examiner has stated that searching the claim as drafted would impose an undue burden.

Applicants therefore respectfully request that the Examiner withdraw the Restriction Requirement and consider the claims of Groups 1-50 together, and consider the claims of Groups 51-100 together.

Restricting a single claim into 50 different inventions is improper

Each of the composition and method claims are divided into 50 Groups, each Group representing a single sequence. However, only two claims list specific SEQ ID NOS; (SEQ ID NOS:1 and 2 of claims 41 and 42). The other 47 sequences that make up the remaining Groups are not even listed in the claims.

It has long been held that an Examiner may not reject a particular claim on the basis that it represents "independent and distinct" inventions. *See, In Re Weber, Soder and Boksay*, 198 USPQ 328, 331 (CCPA 1978) (emphasis added). *See also, In Re Haas*, 179 USPQ 623, 624, 625 (*In Re Haas I*) and *In Re Haas*, 198 USPQ 334-337 (*In Re Haas II*). The courts have definitively ruled that the statute authorizing restriction practice, *i.e.*, 35 U.S.C. § 121, provides no legal authority to impose a restriction requirement on a single claim, even if the claim presents multiple independently patentable inventions. *See, In Re Weber, Soder and Boksay, In Re Haas I and In Re Haas II.* In the cases set forth above, the courts expressly ruled that there is no statutory basis for rejecting a claim for misjoinder,

despite previous attempts by the Patent Office to fashion such a rejection. As noted in *In Re Weber, Soder and Boksay*:

The discretionary power to limit one applicant to one invention is no excuse at all for refusing to examine a broad generic claim-- no matter how broad, which means no matter how many independently patentable inventions may fall within it.

See, In Re Weber, Soder and Boksay at 334.

Alleging that a particular claim represents multiple "patentably distinct" inventions is a *de facto* rejection of the patentability of the claim, because the claim cannot issue as drafted. As the CCPA has noted:

As a general proposition, an applicant has a right to have each claim examined on the merits. If an applicant submits a number of claims, it may well be that pursuant to a proper restriction requirement, those claims will be dispersed to a number of applications. Such action would not affect the rights of the applicant eventually to have each of the claims examined in the form he considers to best define his invention. If, however, a single claim is required to be divided up and presented in several applications, that claim would never be considered on the merits. The totality of the resulting fragmentary claims would not necessarily be the equivalent of the original claim. Further, since the subgenera would be defined by the examiner, rather than by the applicant, it is not inconceivable that a number of the fragments would not be described in the specification.

See, In Re Weber, Soder and Boksay, Supra.

Instead of improperly imposing a restriction requirement on a given claim, the Office may limit initial examination to a "reasonable number" of species encompassed by the claim. *See*, 37 C.F.R. § 1.146. This practice strikes an appropriate balance between the concerns of the Patent Office regarding administrative concerns and unduly burdensome examination, and the clear constitutional and statutory rights of an

inventor to claim an invention as it is contemplated, provided the dictates of 35 U.S.C. § 112 are complied with. *See*, the MPEP at 803.02. *See also*, *In Re Wolfrum* 179 USPQ 620 (C.C.P.A. 1973) and *In re Kuehl* 177 U.S.P.Q. 250 (C.C.P.A. 1973).

Unlike a restriction requirement, a species election does not preclude an applicant from pursuing the original form of a claim in subsequent prosecution, nor does it force an applicant to file multiple divisional applications which are incapable of capturing the intended scope of the application. It should be clear that the added costs of filing and prosecuting 100 patent applications (instead of two patent applications, one for compositions and one for methods) in the present case do not strike an appropriate balance between the administrative concerns of the Office and Applicants' statutory rights as inventors.

Searching the claims together would not present an undue burden

According to the MPEP, where claims can be examined together without undue burden, the Examiner *must* examine the claims on the merits even though they are directed to independent and distinct inventions. *See*, the MPEP at 803.01. In establishing that an "undue burden" would exist for co-examination of claims, the Examiner *must* show that examination of the claims would involve substantially different prior art searches, making the co-examination burdensome. To show undue burden resulting from searching difficulties, the Examiner *must* show that the restricted groups have a separate classification, acquired a separate status in the art, or that searching would require different fields of search (MPEP at § 808.02).

In the present restriction, the Examiner has provided only cursory statements as to why Groups 1-50 and Groups 51-100, respectively, cannot be examined together. For Groups 1-50, the sequences are all listed in the same class and subclass. Similarly, the sequences of Groups 51-100 are listed in the same class and subclass. Although the Examiner admits that the "some" of the inventions classify in the same subclass, "a separate search is required because the sequences present in each of the products is [sic] distinct from one another." Office Action, page 13, lines 4-5. This

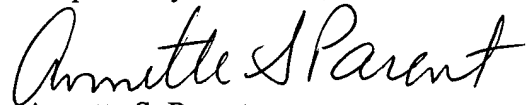
reasoning is cursory and does not explain why the claims should be restricted into groups classified in the same class and subclass. Applicants suggest that the proper method of searching the claim is to request a species election.

The Examiner has not provided any reasoning to show why examining the claims would lead to a burdensome search of the prior art. The Examiner has provided no reasoning to show that the 50 Groups (50 each for methods and compositions) meet the other two criteria required under §808.02, such as a showing that the groups have a separate classification. Applicants therefore respectfully request that the requirement be withdrawn.

Conclusion

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 925-472-5000.

Respectfully submitted,



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